



December 18, 2019

Thomas Graves
Director of Grants Management
Office of Financial Resources, SAMHSA
Room 17E20, 5600 Fishers Lane, Rockville, MD 20857
Email: MJQuestions@SAMHSA.HHS.GOV

Subject: SAMHSA Attestation Requirement

Dear Mr. Graves:

The Council on Governmental Relations (COGR) is an association of 187 research universities and affiliated academic medical centers and independent research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

Several of our member institutions have voiced concerns about a separate attestation SAMHSA now requires as part of the acceptance process for receiving an award. Grantees are required to certify that the grantee organization/recipient, State and all sub-recipients (contractors and sub-awardees) comply with the following Special Term of Award:

Grant funds may not be used, directly or indirectly, to purchase, prescribe, or provide marijuana or treatment using marijuana. Treatment in this context includes the treatment of opioid use disorder. Grant funds also cannot be provided to any individual who or organization that provides or permits marijuana use for the purposes of treating substance use or mental disorders. See, e.g., 45 C.F.R. § 75.300(a) (requiring HHS to “ensure that Federal funding is expended . . . in full accordance with U.S. statutory . . . requirements.”); 21 U.S.C. §§ 812(c)(10) and 841 (prohibiting the possession, manufacture, sale, purchase or distribution of marijuana). This prohibition does not apply to those providing such treatment in the context of clinical research permitted by the DEA and under an FDA-approved investigational new drug application where the article being evaluated is marijuana or a constituent thereof that is otherwise a banned controlled substance under federal law.

This required attestation is not only duplicative of existing requirements of federal law, but also extends beyond such requirements to create additional burdens on research institutions without regulatory authority. The provisions of 45 CFR 75.300 set forth the existing federal requirements, which are intended to ensure that federal funding is spent, and funded programs are implemented, in accordance with law:

- (a) The federal awarding agency must manage and administer the federal award in a manner so as to ensure that federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements: Including, but not limited to, those protecting public welfare, the environment, and prohibiting discrimination. The federal awarding agency must communicate to the non-federal entity all relevant*

public policy requirements, including those in general appropriations provisions, and incorporate them either directly or by reference in the terms and conditions of the federal award.

(b) The non-federal entity is responsible for complying with all requirements of the federal award. For all federal awards, this includes the provisions of FFATA, which includes requirements on executive compensation, and also requirements implementing the Act for the non-Federal entity at 2 CFR part 25 and 2 CFR part 170. See also statutory requirements for whistleblower protections at 10 U.S.C. 2324 and 2409, and 41 U.S.C. 4304, 4310, and 4712.

Accordingly, recipients of federal funds must comply with all applicable federal laws in the management and administration of the award and provide granting agencies with assurances of such compliance – and our member institutions are entirely willing to do so. However, the attestation now being required by SAMHSA includes restrictions much broader than what the law requires. Whereas 45 CFR 75.300 requires that there be a clear link between the regulatory requirement and the federal funds being provided, the new attestation exceeds SAMHSA’s legislative mandate by restricting activities unrelated to the use of the grant funds being provided, *i.e.* the institution’s (or any of its employees’, representatives’ or contractors’) permitting or providing marijuana use for the purposes of treating substance use or mental disorders *regardless of whether the grant funds would be used for such purpose.*

In particular, the “permit” language in the attestation is both vague and apparently is being interpreted very broadly by SAMHSA. We understand (via Corey O. Sullivan in response to an inquiry by one of our member institutions) that SAMHSA believes institutions have an obligation to determine if persons participating in SAMHSA programs have a state medical marijuana card for which the person may be obtaining medical marijuana under state law. Such a requirement is beyond the scope of federal law and would be extremely difficult, if not impossible, for universities to administer. We are further concerned that university-employed physicians who certify that a patient has a medical condition for which the patient may legally obtain medical marijuana (*i.e.*, from a state authorized dispensary) could be deemed to be “permitting” marijuana use for purposes of the new attestation. If such a result is SAMHSA’s intent, we fail to see how this restriction serves the legislative purpose of regulating the use of federal funds. Moreover, as a practical matter, universities simply lack the means to track whether their affiliated physicians choose to certify patients seeking medical marijuana under applicable state laws. Nor do universities (even those that are part of a state system) have any ability to provide an attestation on behalf of the State as a whole.

Beyond the burdensome and overreaching nature of this attestation, it functions in direct contradiction to the increasingly urgent need to reduce barriers to research that may identify antidotes for the harmful effects of drugs. This need was highlighted in the Report of the Committee on Appropriations, House of Representatives, May 15, 2019 addressed the Barriers to Research as follows:

The Committee is concerned that restrictions associated with Schedule I of the Controlled Substance Act effectively limit the amount and type of research that can be conducted on certain Schedule I drugs, especially marijuana or its component chemicals and new synthetic drugs and analogs. At a time when we need as much information as possible about these drugs to find antidotes for their harmful effects, we should be lowering regulatory and other barriers to conducting this research. The Committee directs NIDA to provide a short report on the barriers to research that result from the classification of drugs and compounds as Schedule I substances.

While we recognize SAMHSA created a carveout for “*clinical research permitted by the DEA and under an FDA-approved investigational new drug application,*” not all such vital research necessarily occurs in the context of a prospective, FDA-

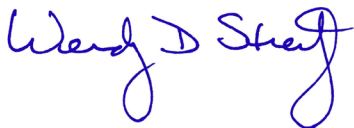
approved clinical investigation. Such research studies may, for example, involve persons in the community who are using medical marijuana under state law schemes, and research involving such populations may yield important information about the risks or benefits of such use on a range of mental health conditions.

For the above stated reasons, COGR requests that SAMHSA remove the new attestation requirement from all awards. If there is a compelling need for an attestation that is not readily apparent, then please consider revising the attestation language to address these concerns. The following is a proposed edited attestation for your consideration. Additionally, in order to eliminate the extra administrative step for both SAMHSA and funding recipients, it would be far preferable to include this as a term and condition of the award rather than a separate attestation.

“These grant funds may not be used, directly or indirectly, to purchase, prescribe, or provide marijuana or treatment using marijuana in a manner that is inconsistent with Federal law. See, e.g., 45 C.F.R. § 75.300(a) (requiring HHS to “ensure that Federal funding is expended . . . in full accordance with U.S. statutory . . . requirements.”); 21 U.S.C. §§ 812(c)(10) and 841 (prohibiting the possession, manufacture, sale, purchase or distribution of marijuana). This prohibition does not apply to those providing such treatment in the context of clinical research permitted by the DEA and under an FDA-approved investigational new drug application where the article being evaluated is marijuana or a constituent thereof that is otherwise a banned controlled substance under federal law. Grantees are responsible for ensuring that all subawardees involved in this grant program comply with the requirements of this certification.”

We look forward to hearing from you. Please feel free to contact Jackie Bendall at (202) 289-6655, x 117 or jbendall@cogr.edu if you have any questions.

Sincerely,

A handwritten signature in blue ink that reads "Wendy D. Streitz". The signature is fluid and cursive, with the first and last names being the most prominent.

Wendy D. Streitz
President